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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/624.201

07/21/2003

David J. Hannapel

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1454

7590

06/14/2006

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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/624,201	Applicant(s) HANNAPEL ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 and 43-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 and 43-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed 3/27/2006 has been entered.
2. Claims 1-25 and 43-68 are pending.
Claims 26-42 have been canceled.
Claims 57-68 have been newly added.
3. Newly submitted claims 57-68 are drawn to many nucleic acid and amino acid sequences. In the restriction requirement mailed 6/16/2005, Applicant was requested to elect one DNA and one corresponding amino acid sequence.

Applicant is reminded that nucleotide sequences either encoding different proteins or specifying specific expression patterns are structurally distinct chemical compounds and are unrelated to one another, as are different proteins structurally distinct chemical compounds and unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq (see MPEP 803.04 and 2434). This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

4. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-25 and 43-68 drawn to SEQ ID NO:1 encoding SEQ ID NO:2 are examined in the present office action. See 37 CFR 1.142(b) and MPEP § 821.03.

5. Rejections and objections not set forth below are withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Objection

7. Claims 2-6, 13-16, 20-23, 44-47, and 51-54 remain objected to and claims 1, 7-12, 17-19, 24-25, 43, 48-50, 55-68 are objected for being drawn to non-elected inventions. The objection includes dependent claims. This objection is maintained for the reasons of record set forth in the Official action mailed 9/23/2005. Applicant's arguments filed 3/27/2006 have been fully considered but they are not persuasive.

Applicants contend that the basis for the objection is the inclusion of SEQ ID NO:3-14 in the examined claims. Applicants contend that up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction, see MPEP §803.04 (page 17 of Remarks, 3rd and 4th paragraphs). Applicants contend, based on the foregoing, the restriction requirement should be withdrawn (page 17 of Remarks, 4th paragraph).

The Office contends that the restriction requirement was made final in the office action mailed 9/23/2005. Applicants have the prerogative to petition the restriction decision.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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8. Claims 1-25 and 43-68 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection includes dependent claims.

Claim 1 is indefinite for reciting “90% similar to a nucleotide sequence”. In claim 1, Applicants also recite “similar” in regards to amino acid sequences. Applicants have not defined “similar” in regards to nucleotide or amino acid sequences and therefore, one skilled in the art would not be apprised of the metes and bounds of “similar”. All subsequent recitations of “similar” are also rejected.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-25 and 43-68 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid molecule encoding a BEL transcription factor from *Solanum tuberosum* wherein said nucleic acid molecule comprises a nucleotide sequence of SEQ ID NO:1, or comprises a nucleotide sequence that is at least 90% similar to a nucleotide sequence of SEQ ID NO:1 and that encodes a protein that is at least 90% similar to a homeodomain region, a SKY box, a BELL domain, and a VSLTLGL-box in SEQ ID NO:2, or

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comprises a nucleotide sequence that hybridizes to the nucleic acid sequence of SEQ ID NO:1 under stringent conditions as recited in claim 1(c) or encodes a protein or polypeptide comprising an amino acid sequence of SEQ ID NO:2; a DNA construct, expression vector, host cell, transgenic plant, transgenic plant seed, a method for increasing rate of growth of a plant, and method for regulating flowering in a plant, comprising said nucleic acid molecule.

The Office interprets “a nucleotide sequence of SEQ ID NO:1” to read on a large number of sequences because the Office interprets said recitation to encompass nucleic acid molecules comprising any portion of SEQ ID NO:1 because of the article “a”.

The Office interprets “an amino acid sequence of SEQ ID NO:2” to read on a large number of sequences because the Office interprets said recitation to encompass nucleic acid sequences that encode any portion of SEQ ID NO:2.

Because of the indefiniteness of “similar” as discussed above, the claims are interpreted to read on any nucleic acid molecule that encodes a *Solanum tuberosum* transcription factor.

Applicants disclose the isolation of StBEL-05 from *Solanum tuberosum* using a two-hybrid selection system in yeast using the POTH1 (potato homeobox cDNA) in the GAL4-binding domain vector (page 89, lines 20-31). Applicants disclose the cDNA sequence of StBEL-05 is set forth in SEQ ID NO:1 encoding the deduced amino acid sequence of SEQ ID NO:2 (page 22, paragraphs 55-56). Applicants disclose that StBEL-05 is a novel BEL type of transcription factor in the TALE superclass. StBEL-05 comprises a homeodomain region encompassing helices I, II, and III, the amino-terminal SKY box consisting of 20 amino acids (from ser 207 to lys-226 in StBEL-05), the 120 amino acid domain starting at leu-272 of the StBEL-05 sequence, and the carboxy-terminal VSLTLGL-box (SEQ ID NO:15) beginning at

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val-620 (paragraph 164, bridging pages 90-91). The deduced lengths of the seven original cDNAs isolated in the yeast two-hybrid screen are 688 aa for StBEL-05, 535 aa for StBEL-11, 586 aa for StBEL-13, 589 aa for StBEL-14, 620 aa for StBEL-22, 567 aa for StBEL-29, and 645 aa for StBEL-30. Five'-RACE was used to verify the full-length of StBEL-05, -13, -14 and -30. Southern blot analysis revealed that these genes are unique and belong to small gene subfamilies, based on the complexity of bands detected by gene-specific probes from each of the cDNAs (Figure 13C) (page 91, paragraph 165).

The Applicants do not identify essential regions that are unique to StBEL-05 proteins encoded by SEQ ID NO:1, nor do Applicants describe any polynucleotide sequences that hybridize to SEQ ID NO:1 under the specified conditions and encode a BEL transcription factor from *Solanum tuberosum* whose amino acid sequence is SEQ ID NO:2. In addition, Applicants' claims drawn to percent similarity or hybridization do not include an activity for the encoded protein or polypeptide.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural

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features common to members of the genus, which features constitute a substantial portion of the genus.” See *University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences encoding a StBEL-05 protein from *Solanum tuberosum* falling within the scope of the claimed genus of polynucleotides which encode any BEL transcription factor from *Solanum tuberosum*.

Applicants only describe a single cDNA sequence of SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*.

Furthermore, given the lack of description of the necessary elements essential for the StBEL-05 protein encoded by SEQ ID NO:1, it remains unclear what features identify a StBEL-05 protein from *Solanum tuberosum*. Since the genus of StBEL-05 proteins encoded by SEQ ID NO:1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breadth of the claims.

Applicant's arguments filed 3/27/2006 have been fully considered but they are not persuasive.

Applicants contend that the specification discloses other BEL transcription factors from *Solanum tuberosum* and that the disclosed sequences contain a homeodomain region, a SKY box region, a BELL domain region and a VSLTLGL-box region, each of which is discussed in more detail within the specification (paragraph bridging pages 19 and 20 of Remarks).

Applicants contend that the amended claims recite that the isolated sequences must have a nucleotide sequence that is “at least 90% similar” to one of the other sequences and also encode

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a protein having at least 90% similarity to the recited regions (page 20 of Remarks, 1st full paragraph). Applicants contend the amended claims now recite high stringency hybridization conditions (page 20 2nd full paragraph). Applicants contend the present specification discloses a representative number of sequences and structural or other physical and/or chemical properties (page 21 of Remarks, 1st paragraph).

The Office acknowledges that Applicants have identified regions that are conserved among the seven *Solanum tuberosum* BEL transcription factors but Applicants have not addressed if all seven transcription factors have the same activity when transformed into a plant and produce plants with the same phenotype. Unless demonstrated differently, the Office contends that the seven BEL transcription factors do not all have the same activity. Therefore, Applicants need to disclose regions of SEQ ID NO:2 that are unique and essential to the protein encoded by SEQ ID NO:1.

Scope of Enablement

10. Claims 1-25 and 43-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid molecule of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:2, a DNA construct and expression vector comprising said isolated nucleic acid molecule; and host cell, transgenic plant, and transgenic plant seed transformed with the isolated nucleic acid molecule, does not reasonably provide enablement for an isolated nucleic acid molecule encoding a BEL transcription factor from *Solanum tuberosum* wherein said nucleic acid molecule comprises a nucleotide sequence of SEQ ID NO:1, or comprises a nucleotide sequence that is at least 90% similar to a nucleotide sequence of SEQ ID

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NO:1 and that encodes a protein that is at least 90% similar to a homeodomain region, a SKY box, a BELL domain, and a VSLTLGL-box in SEQ ID NO:2, or comprises a nucleotide sequence that hybridizes to the nucleic acid sequence of SEQ ID NO:1 under stringent conditions as recited in claim 1(c) or encodes a protein or polypeptide comprising an amino acid sequence of SEQ ID NO:2; a DNA construct, expression vector, host cell, transgenic plant, transgenic plant seed, a method for increasing rate of growth of a plant, and method for regulating flowering in a plant, comprising said nucleic acid molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid molecule encoding a BEL transcription factor from *Solanum tuberosum* wherein said nucleic acid molecule comprises a nucleotide sequence of SEQ ID NO:1, or comprises a nucleotide sequence that is at least 90% similar to a nucleotide sequence of SEQ ID NO:1 and that encodes a protein that is at least 90% similar to a homeodomain region, a SKY box, a BELL domain, and a VSLTLGL-box in SEQ ID NO:2, or

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comprises a nucleotide sequence that hybridizes to the nucleic acid sequence of SEQ ID NO:1 under stringent conditions as recited in claim 1(c) or encodes a protein or polypeptide comprising an amino acid sequence of SEQ ID NO:2; a DNA construct, expression vector, host cell, transgenic plant, transgenic plant seed, a method for increasing rate of growth of a plant, and method for regulating flowering in a plant, comprising said nucleic acid molecule.

The Office interprets “a nucleotide sequence of SEQ ID NO:1” to read on a large number of sequences because the Office interprets said recitation to encompass nucleic acid molecules comprising any portion of SEQ ID NO:1 because of the article “a”.

The Office interprets “an amino acid sequence of SEQ ID NO:2” to read on a large number of sequences because the Office interprets said recitation to encompass nucleic acid sequences that encode any portion of SEQ ID NO:2.

Because of the indefiniteness of “similar” as discussed above, the claims are interpreted to read on any nucleic acid molecule that encodes a *Solanum tuberosum* transcription factor.

Applicants disclose the isolation of StBEL-05 from *Solanum tuberosum* using a two-hybrid selection system in yeast using the POTH1 (potato homeobox cDNA) in the GAL4-binding domain vector (page 89, lines 20-31). Applicants disclose the cDNA sequence of StBEL-05 is set forth in SEQ ID NO:1 encoding the deduced amino acid sequence of SEQ ID NO:2 (page 22, paragraphs 55-56). Applicants disclose that StBEL-05 is a novel BEL type of transcription factor in the TALE superclass. StBEL-05 comprises a homeodomain region encompassing helices I, II, and III, the amino-terminal SKY box consisting of 20 amino acids (from ser 207 to lys-226 in StBEL-05), the 120 amino acid domain starting at leu-272 of the StBEL-05 sequence, and the carboxy-terminal VSLTLGL-box (SEQ ID NO:15) beginning at

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val-620 (paragraph 164, bridging pages 90-91). The deduced lengths of the seven original cDNAs isolated in the yeast two-hybrid screen are 688 aa for StBEL-05, 535 aa for StBEL-11, 586 aa for StBEL-13, 589 aa for StBEL-14, 620 aa for StBEL-22, 567 aa for StBEL-29, and 645 aa for StBEL-30. Five'-RACE was used to verify the full-length of StBEL-05, -13, -14 and -30. Southern blot analysis revealed that these genes are unique and belong to small gene subfamilies, based on the complexity of bands detected by gene-specific probes from each of the cDNAs (Figure 13C) (page 91, paragraph 165). Applicants disclose that a 2000-bp fragment of the coding sequence of StBEL-05 in a sense orientation driven by the CaMV-35S promoter was transformed into potato (page 94, paragraph 169). The highest expressers of StBEL-05 sense transcripts exhibited tuber formation under LD conditions whereas control plants produced tubers only under SD conditions. The highest overexpressers of StBEL-05 also produced more tubers than control plants and were more responsive to inductive conditions. Tubers from overexpressers grew larger than controls. Applicants disclose that plants overexpressing StBEL-05 were taller and had a greater weight compared to control plants (page 97, Table 4).

Re: claim 50 is drawn to a method for regulating flowering in a plant. Applicants have not disclosed by way of example or disclosure, that their invention has any effect or influence on flowering.

Applicants claims are drawn to nucleic acid sequences that hybridize to SEQ ID NO:1, but the state-of-the-art teaches isolating DNA fragments using stringent hybridization conditions, does not always select for DNA fragments whose contiguous nucleotide sequence is the same or nearly the same as the probe. Fourgoux-Nicol et al (1999, Plant Molecular Biology 40 :857-872) teach the isolation of a 674bp fragment using a 497bp probe incorporating stringent

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hybridization conditions comprising three consecutive 30 minute rinses in 2X, 1X and 0.1X SSC with 0.1% SDS at 65°C (page 859, left column, 2nd paragraph). Fourgoux-Nicol et al also teach that the probe and isolated DNA fragment exhibited a number of sequence differences comprising a 99bp insertion and a single nucleotide gap, while the DNA fragment contained 2 single nucleotide gaps and together the fragments contained 27 nucleotide mismatches. Taking into account the insertions, gaps and mismatches, the longest stretch of contiguous nucleotides to which the probe could hybridize consisted of 93bp of DNA (page 862, Figure 2).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that hybridize under stringent conditions to SEQ ID NO:1 will encode a protein with the same activity as a protein encoded by SEQ ID NO:1. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

The state-of-the-art teaches that transforming plants with homeobox transcription factors produces unexpected results. Chuck et al (1996, The Plant Cell 8:1277-1289) teach transforming Arabidopsis plants with the Arabidopsis knotted1-like gene, KNAT1, produced plants with

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abnormal phenotypes. The transformed plants exhibited large, severely lobed leaves, some of which comprised ectopic shoot meristems in the sinus region, small flowers with thin, elongated, greenish petals that abscised early and anthers that dehisced later than normal, and vascular tissue that developed aberrantly (page 1278, left column, 1st paragraph of results; page 1279, Figure 1C and right column; page 1280, left column, 1st paragraph).

Applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by Applicants' broad claims. Applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences.

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:1 as probes or by designing primers to undisclosed regions of SEQ ID NO:2 and isolating or amplifying fragments, subcloning the fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that when over-expressed produce a potato plant with increased number and weight of tubers.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Applicant's arguments filed 3/27/2006 have been fully considered but they are not persuasive.

Applicants contend regarding claim 50 that they are not required to present experimental data regarding methods of use. Applicants requested clarification if additional data can be used to obviate the rejection (page 22 of Remarks, 2nd full paragraph).

The Office invites Applicants to submit additional data in the form of a 1.132 declaration.

Applicants contend the present claims have been amended to recite high stringency conditions which are more stringent than those conditions recited by Fourgoux-Nicol (paragraph bridging pages 22 and 23 of Remarks).

The Office contends that Applicants have not included a functional limitation. Therefore, the claims read upon any sequence that would hybridize regardless of the encoded proteins activity.

Applicants do not agree with the following statements recited by the USPTO office:

“...one of skill in the art cannot predict which nucleic acids that hybridize under stringent conditions to SEQ ID NO:1 will encode a protein with the same activity as a protein encoded by SEQ ID NO:1 (Office Action, at page 10). ...the state-of-the-art teaches that transforming plants with homeobox transcription factors produces unexpected results (Office Action, at page 10). ...applicants note that the USPTO's support for this is based on research using the Arabidopsis knotted1-like gene (KNAT1). ...applicants have not disclosed how one makes or isolates any of the sequences that are encompassed by applicants' “broad claims” (Office Action, at page 11, lines 1-2). ...applicants have not taught which regions of the respective polynucleotides can be used to amplify any of said polynucleotides or which regions can be used as a probe to isolate any of said polynucleotide sequences” (page 23 of Remarks, bottom paragraph).

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The Office contends that given the state-of-the-art as discussed above, the level of unpredictability as stated above, the lack of examples or guidance, and the claim breadth, undue trial and error experimentation would be required by one of skill in the art to make and/or use the claimed invention.

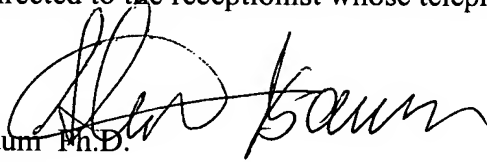
11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
June 5, 2006



STUART F. BAUM, PH.D.
PATENT EXAMINER